Institute for Apprenticeships & Technical Education

End-point assessment plan for Clinical Pharmacology Scientist apprenticeship standard

Apprenticeship standard number	Apprenticeship standard level	Integrated end-point assessment
ST0798	7	Integrated degree apprenticeship

Contents

Introduction and overview

This document sets out the requirements for end-point assessment (EPA) for the Clinical Pharmacology Scientist apprenticeship standard. It is for end-point assessment organisations (EPAOs) who need to know how EPA for this apprenticeship must operate. It will also be of interest to Clinical Pharmacology Scientist apprentices, their employers and training providers.

This is an integrated degree apprenticeship of 180 credits in total, the MSc Clinical Pharmacology degree incorporates on-programme academic and workplace learning and assessment with an independent EPA to test the occupational standard's KSBs (Knowledge, Skills, and Behaviours). The EPA accounts for 20 credits.

Full time apprentices will typically spend 30 months on-programme (before the gateway) working towards the occupational standard, with a minimum of 20% off-the-job training. All apprentices must spend a minimum of 12 months on-programme.

The EPA period should only start, and the EPA be arranged, once the employer is satisfied that the apprentice is deemed to be consistently working at or above the level set out in the occupational standard, all of the pre-requisite gateway requirements for EPA have been met and can be evidenced to an EPAO.

As a gateway requirement and prior to taking the EPA, apprentices must achieve 160 credits of the qualification mandated in the Clinical Pharmacology Scientist occupational standard.

This is:

- MSc in Clinical Pharmacology

For level 3 apprenticeships and above, apprentices without English and mathematics at level 2 must achieve level 2 prior to taking their EPA.

The EPA must be completed within an EPA period, lasting typically 6 months after the EPA gateway.

The EPA consists of 2 discrete assessment methods.

The individual assessment methods will have the following grades:
Assessment method 1: Project and presentation

- Fail
- Pass
- Distinction

Assessment method 2: Professional discussion underpinned by portfolio

- Fail
- Pass
- Distinction

Performance in the EPA will determine the overall apprenticeship standard grade of:

- Fail
- Pass
- Merit
- Distinction

EPA summary table

On-programme (typically 30 months)	Training to develop the occupation standard's knowledge, skills and behaviours (KSBs). • Compiling a portfolio of evidence.
End-point assessment gateway	Employer is satisfied the apprentice is consistently working at, or above, the level of the occupational standard. Apprentices must achieve the following approved qualifications mandated in the occupational standard: • 160 credits of the MSc in Clinical Pharmacology • English and mathematics Level 2 Apprentices must submit: • A portfolio to support the professional discussion.
End-point assessment (which will typically take 6 months)	Assessment method 1: Project and presentation With the following grades: • Fail • Pass • Distinction Assessment method 2: Professional discussion underpinned by portfolio With the following grades: • Fail • Pass • Distinction Performance in the EPA will determine the overall apprenticeship standard grade of: • Fail • Pass • Merit • Distinction These equate to 20 credits of the MSc in Clinical Pharmacology
Professional recognition	Aligns with recognition by: • Full membership of the British Pharmacological Society

Length of end-point assessment period

The EPA will be completed within an EPA period lasting typically 6 months after the EPA gateway, starting when the EPAO has confirmed that all gateway requirements have been met.

Order of assessment methods

The assessment methods can be delivered in any order.

EPA gateway

The EPA period should only start once the employer is satisfied that the apprentice is consistently working at, or above, the level set out in the occupational standard, and are deemed to have achieved occupational competence. In making this decision, the employer may take advice from the apprentice's training provider(s), but the decision must ultimately be made solely by the employer.

In addition to the employer's confirmation that the apprentice is working at or above the level in the occupational standard, the apprentice must have completed the following gateway requirements prior to beginning EPA:

- 160 credits of the MSc in Clinical Pharmacology
- English and mathematics at level 2

For those with an education, health and care plan or a legacy statement the apprenticeships English and mathematics minimum requirement is Entry Level 3 and British Sign Language qualification are an alternative to English qualifications for whom this is their primary language.

For Project and presentation:

- the project's subject, title and scope are to be agreed between the employer and the EPAO at the gateway and will be signed off by the EPAO.

For Professional discussion underpinned by portfolio the apprentice will be required to submit:

- A completed portfolio of evidence

The portfolio of evidence requirements are as follows:

- apprentices must compile a portfolio of evidence during the on-programme period of the apprenticeship
- it should not include reflective accounts or any methods of self-assessment
- any employer contributions should focus on direct observation of performance (e.g. witness statements) rather than opinions
- the evidence provided must be valid and attributable to the apprentice; the portfolio of evidence must contain a statement from the employer and apprentice confirming this
- the portfolio of evidence must be submitted to the EPAO at the gateway
- The format and structure of the portfolio needs to be agreed between the employer, the apprentice and the EPAO (e.g. hard copy or on-line). However, the content must be sufficient to evidence the apprentice can apply the knowledge, skills and behaviours required as mapped to assessment method two (AM2).
- There must be at least one piece of evidence relating to each knowledge, skill and behaviour mapped to AM2. One piece of evidence can be referenced against more than one knowledge,

skill or behavioural requirement; a qualitative as opposed to quantitative approach is suggested. It is expected that there will typically be 30 pieces of evidence.

- The portfolio should contain written accounts of activities that have been completed and referenced against the knowledge, skills and behaviours mapped to the professional discussion, supported by appropriate evidence. This can include photographic evidence and work materials, such as work instructions, safety documentation, company policies and procedures as appropriate to the activities. Progress review documentation, witness testimonies, and feedback from colleagues and/or clients can also be included. The apprentice's Manager/Mentor will typically support the development of the portfolio in accordance with company policy and procedures, although the end-point assessment organisation will provide further guidance on the typical content.

The portfolio is not directly assessed. It underpins the professional discussion assessment method and therefore should not be marked by the EPAO. EPAOs should review the portfolio of evidence in preparation for the Professional Discussion but are not required to provide feedback after this review of the portfolio.

End-point assessment methods

Assessment method 1: Project and presentation (This assessment method has 2 components.)

Assessment method 1 component 1: Project

Overview

The project is compiled after the apprentice has gone through the gateway.

The work-based project should be designed to ensure that the apprentice's work meets the needs of the business, is relevant to their role and allows the relevant KSBs to be demonstrated for the EPA. Therefore, the project's subject, title and scope will be agreed between the employer and the EPAO at the gateway. The employer will ensure it has a real business application and the EPAO will ensure it meets the requirements of the EPA (including suitable coverage of the KSBs assignment to this assessment method). The EPAO should sign-off the project subject, title and scope to confirm its suitability prior to the project commencing.

The rationale for this assessment method is:

The occupation of Clinical Pharmacology Scientist involves delivering projects as part of the day-to-day role. The use of a project for assessment is, therefore, considered to be the best method of assessment and shows the use of KSBs in practice.

Delivery

Apprentices will conduct a project in the form of a report.

The project starts after the apprentice has gone through the gateway. The typical duration of the project should be 16 weeks.

Within this time, the employer will ensure the apprentice has sufficient time and the necessary resources to plan and undertake the project.

The project should be either paper-based or in an electronic format.

The project may be based on a critical appraisal of a post-gateway piece of work involving the role of the clinical pharmacologist, such as:

- Study which has reached final or interim analysis
- Meta-analysis of studies
- Submission package
- Clinical trial report
- Development of clinical pharmacology programme

As part of the critical appraisal, the apprentice could:

- Comment on the validity of the methods of analysis, data interpretation and data presentation
- Advise whether an alternative approach could have been considered
- Comment on the learnings

- Advise upon whether it could have been completed in a more cost or time efficient manner
- Comment on the learnings derived
- Recommend any process improvements

As a minimum, all projects must include:

- An executive summary
- An introduction
- The scope of the project (including key performance indicators)
- Research and findings
- Project outcomes
- Recommendations and conclusions

The project must map, in an appendix, how it evidences the relevant KSBs for this assessment method. This is not included in the word count.

The word count is normally 9,000 words including an executive summary which can be understood by a non-technical audience.

A tolerance of plus or minus 10% is allowed at the apprentice's discretion.

Appendices, references and diagrams are not included in the total word limit.

The apprentice will have 16 weeks to write and submit the project report and presentation following the EPAO's approval of the project report's scope and title.

The project report plus materials relating to the presentation (see below) must be submitted together after the gateway.

The apprentice should complete their project unaided. When the project report is submitted, the apprentice and their employer must verify that the submitted project report and presentation is the apprentice's own work.

Marking

The independent assessor will review and mark the project in a timely manner, as determined by the EPAO, and without extending the EPA unnecessarily. Similarly, all quality control processes will also be conducted in a timely manner, as determined by the EPAO.

The independent assessor will review and assess the project holistically together with the other components of this assessment method.

The independent assessor will make all grading decisions.

Assessment method 1 component 2: Presentation with questioning

Overview

Apprentices will prepare and deliver a presentation that appropriately covers the KSBs assigned to this method of assessment.

The presentation will be based on the project or project report and will cover:

- A summary of the project report
- Explanation of how and why specific techniques and criteria have been selected
- Improvements moving forward
- Recommendations
- Critical evaluation of the project.

The presentation will be completed and submitted after the gateway and will be presented to an independent assessor, either face-to-face or via online video conferencing. Video conferencing can be used to conduct the presentation, but the EPAO must have processes in place to verify the identity of the apprentice and ensure the apprentice is not being aided.

The independent assessor should have 4 weeks to review the report prior to the presentation. The apprentice needs to notify the EPAO at the submission of the project report and presentation of any technical requirements for the presentation component.

Delivery

The presentation will last for 60 minutes, typically including a 30-minute presentation and questioning for 30 minutes. The independent assessor has the discretion to increase the time of the presentation by up to 10% to allow the apprentice to complete their last point.

The independent assessor will ask a minimum of 6 questions at the end of the presentation. The independent assessor will use the questions from a question bank supplied by the EPAO as a guide to tailor their own questions based on the presentation. They will use them to confirm their understanding of the presentation and how it demonstrates the relevant KSBs. Independent assessors are responsible for generating suitable follow-up questions in line with the EPAO's training and standardisation process. The questions relating to underpinning KSBs must be varied yet allow assessment of the relevant KSBs. The independent assessor must use the assessment tools and procedures that are set by the EPAO to record the presentation and questioning.

A question bank must be developed by EPAOs. The 'question bank' must be of sufficient size to prevent predictability and the EPAO must review it regularly (at least once a year) to ensure that it, and its content, are fit for purpose. The specifications, including questions relating to the underpinning KSBs, must be varied yet allow assessment of the relevant KSBs.

EPAOs must ensure that apprentices have a different set of questions in the case of re-sits/re-takes.

Independent assessors must be developed and trained by the EPAO in the conduct of questioning and reaching consistent judgement.

The independent assessor will make all grading decisions. The independent assessor will assess all components of this assessment method holistically.

The questions will be drawn from a question bank supplied by the EPAO, to confirm the independent assessor's understanding of the presentation and how it demonstrates the relevant KSBs.

To deliver the presentation, the apprentice will have access to:

- Notes
- PowerPoint
- Computer
- Work products
- Videos

- Flip charts
- Interactive demonstrations
- Any other requirements as notified to the EPAO on submission of the project report and presentation

Venue

EPAOs must ensure that the presentation and questioning elements are conducted in a suitable, controlled environment in any of the following:

- employer's premises
- other suitable venue selected by the EPAO (e.g. a training provider)
- videoconferencing

The venue should be a quiet room, free from distraction and external influence.

Video conferencing can also be used to conduct the presentation with Q&A, but the EPAO must have processes in place to verify the identity of the apprentice and ensure the apprentice is not being aided.

Supporting material

EPAOs will produce the following materials to ensure that this assessment method is marked consistently and accurately:

- Outline of the assessment method's requirements
- Independent assessor training materials
- Standard documentation for recording of assessment results
- Examples of projects
- Marking materials
- A question bank
- Grading guidance
- A feedback sheet for apprentices who fail this assessment method, giving enough detail to allow the employer and the EPAO to decide whether a new project needs to be undertaken

Assessment method 2: Professional discussion underpinned by portfolio (This assessment method has 1 component.)

Overview

This assessment will take the form of a professional discussion which must be appropriately structured to draw out the best of the apprentice's competence and excellence and cover the KSBs assigned to this assessment method. A professional discussion is a two-way discussion which involves both the independent assessor and the apprentice actively listening and participating in a formal conversation. It gives the apprentice the opportunity to make detailed and proactive contributions to confirm their competency across the KSBs mapped to this method. It will include the questions that will assess the KSBs assigned to this assessment method and the apprentice may use their portfolio to support their responses.

The rationale for this assessment method is:

- it allows the apprentice to be assessed against KSBs which may not naturally occur during the project or presentation
- It enables the apprentice to demonstrate the application of skills and behaviours as well as knowledge
- It allows scope for the apprentice to demonstrate the depth and breadth of KSBs, allowing for a distinction marking.

Delivery

The independent assessors will conduct and assess the professional discussion.

Apprentices must be given at least 4 weeks' notice ahead of the professional discussion. The underpinning portfolio will have been submitted in line with EPAO requirements and at the gateway and must evidence all of the KSBs mapped to this assessment method. The independent assessor can use the contents of the portfolio to identify discussion topics for the professional discussion.

The professional discussion must last for 90 minutes. The independent assessor has the discretion to increase the time of the professional discussion by up to 10% to allow the apprentice to complete their last answer. Further time may be granted for apprentices with appropriate needs, in-line with the EPAO's Reasonable Adjustments policy.

Independent assessors must use the EPAO's question bank as a source for questioning and are expected to use their professional judgment to tailor those questions appropriately. Independent assessors may ask further questions for clarification purposes and to allow the apprentice the opportunity to cover the KSBs mapped to this assessment method.

The professional discussion will be undertaken by an independent assessor. The method is underpinned by the portfolio submitted as a gateway requirement. Questioning should be used to assess KSBs mapped to this method and to explore the apprentice's ability to demonstrate against the KSBs in different circumstances. KSBs should only be assessed once. Apprentices will be expected to refer to examples in their portfolio to support their answers. A minimum of 13 questions should be asked.

The apprentice and the independent assessor will have access to their own copies of the portfolio throughout the professional discussion and both can refer to it as needed.

Independent assessors must be developed and trained in the conduct of professional discussions, how to design their own questions from reviewing portfolio content, and in reaching consistent judgement by their EPAO.

The purpose of the professional discussion is to:

- assess the KSBs mapped to this method
- explore aspects of the work, including how it was carried out, in more detail
- require the apprentice to draw on their evidence to demonstrate the KSBs.

The independent assessor must use the assessment tools and procedures that are set by the EPAO to record the professional discussion. KSBs met, and answers to questions, must be recorded by the independent assessor.

The independent assessor will make all grading decisions.

Venue

The professional discussion should take place in a quiet room, free from distractions and influence.

The professional discussion can take place in any of the following:

- employer's premises
- a suitable venue selected by the EPAO (for example a training provider's premises)
- videoconferencing

Video conferencing can be used to conduct the professional discussion, but the EPAO must have processes in place to verify the identity of the apprentice and ensure the apprentice is not being aided.

Other relevant information

A structured question bank must be developed by EPAOs. The 'question bank' must be of sufficient size to prevent predictability and the EPAO must review it regularly (at least once a year) to ensure that it, and its content, are fit for purpose. The questions relating to the underpinning KSBs, must be varied yet allow assessment of the relevant KSBs.

EPAOs must ensure that apprentices have a different set of questions in the case of re-sits/re-takes.

Independent assessors must be developed and trained by the EPAO in the conduct of professional discussion and reach consistent judgement in line with the EPAO's training and standardisation. process.

EPAOs will produce the following materials to support this assessment method:

- a question bank
- assessment recording documentation
- guidance for apprentices and employers
- grading guidance
- marking materials

Reasonable adjustments

The EPAO must have in place clear and fair arrangements for making reasonable adjustments to the assessment methods for the EPA for this apprenticeship standard. This should include how an apprentice qualifies for reasonable adjustment and what reasonable adjustments will be made. The adjustments must maintain the validity, reliability and integrity of the assessment methods outlined in this end-point assessment plan.

Weighting of assessment methods

All assessment methods are weighted equally in their contribution to the overall EPA grade.

Overall EPA grading

All EPA methods must be passed for the EPA to be passed overall.

Apprentices must gain a pass in both methods to achieve a pass overall. A pass in one method plus a distinction on the other method results in a merit overall. Apprentices must gain a distinction in both assessment methods to gain a distinction overall.

Grades from individual assessment methods should be combined in the following way to determine the grade of the EPA as a whole:

Assessment method 1: Project and Presentation	Assessment method 2: Professional Discussion underpinned by Portfolio	Overall grading
Fail	Any grade	Fail
Any grade	Fail	Fail
Pass	Pass	Pass
Pass	Distinction	Merit
Distinction	Pass	Merit
Distinction	Distinction	Distinction

Any grade = fail, pass, distinction.

Re-sits and re-takes

Apprentices who fail one or more assessment method will be offered the opportunity to take a re-sit or a re-take. A re-sit does not require further learning, whereas a re-take does.

Apprentices should have a supportive action plan to prepare for the re-sit or a re-take. The apprentice's employer will need to agree that either a re-sit or re-take is an appropriate course of action.

An apprentice who fails an assessment method, and therefore the EPA in the first instance, will be required to re-sit or re-take any failed assessment methods only.

The timescales for a re-sit/re-take are agreed between the employer and EPAO. A re-sit is typically taken within 2 months of the EPA outcome notification. The timescale for a re-take is dependent on how much re-training is required and is typically taken within 4 months of the EPA outcome notification. All assessment methods must be taken within a 6 month period of each other otherwise the entire EPA will need to be re-sat/re-taken. If the apprentice fails the project and presentation, subject to feedback, they will have to rework the original project, rather than a new project be set, and may resubmit with changes as a re-sit/re-take. Apprentices will have 4 weeks to complete and submit the resit/retake project and presentation materials, with the EPAO having 2 weeks to review the materials before facilitating the presentation. The feedback can advise an apprentice on the area(s) failed in the EPA, but not advise what they need to do to overcome it in a re-sit or re-take.

Re-sits and re-takes are not offered to apprentices wishing to move from pass to merit or merit to distinction.

Where any assessment method has to be re-sat or re-taken, the apprentice will be awarded a maximum EPA grade of pass, unless the EPAO determines there are exceptional circumstances requiring a re-sit or re-take.

Roles and responsibilities

Role	Responsibility
Apprentice	As a minimum, apprentices should: • participate in and complete on-programme training to meet the KSBs as outlined in the occupational standard for a minimum of 12 months • undertake 20% off-the-job training as arranged by the employer and EPAO • understand the purpose and importance of EPA • undertake the EPA including meeting all gateway requirements
Employer	As a minimum, employers should: • select the EPAO and training provider • work with the training provider (where applicable) to support the apprentice in the workplace and to provide the opportunities for the apprentice to develop the KSBs • arrange and support a minimum of 20% off-the-job training to be undertaken by the apprentice • decide when the apprentice is working at, or above, the occupational standard and so is ready for EPA • ensure that all supporting evidence required at the gateway is submitted in accordance with this EPA plan • remain independent from the delivery of the EPA • confirm arrangements with the EPAO for the EPA (who, when, where) in a timely manner (including providing access to any employer-specific documentation as required, e.g. company policies) • ensure that the EPA is scheduled with the EPAO for a date and time that allow appropriate opportunity for the KSBs to be met • ensure the apprentice is well prepared for the EPA • ensure the apprentice is given sufficient time away from regular duties to prepare for and complete all post-gateway elements of the EPA, and that any required supervision during this time (as stated within this EPA plan) is in place • where the apprentice is assessed in the workplace, ensure that the apprentice has access to the resources used on a daily basis

	• pass the certificate to the apprentice
EPAO	As a minimum EPAOs should: • conform to the requirements of this EPA plan and deliver its requirements in a timely manner • conform to the requirements of the Register of End-Point Assessment Organisations (RoEPAO) • conform to the requirements of the external quality assurance provider (EQAP) for this apprenticeship standard • understand the occupational standard • make all necessary contractual arrangements, including agreeing the price of the EPA • develop and produce assessment materials including specifications and marking materials (e.g. mark schemes, practice materials, training materials) • appoint suitably qualified and competent independent assessors • appoint administrators (and invigilators where required) to administer the EPA as appropriate • provide training for independent assessors in terms of good assessment practice, operating the assessment tools and grading • provide adequate information, advice and guidance documentation to enable apprentices, employers and training providers to prepare for the EPA • arrange for the EPA to take place, in consultation with the employer • where the apprentice is not assessed in the workplace, ensure that the apprentice has access to the required resources and liaise with the employer to agree this if necessary • develop and provide appropriate assessment recording documentation to ensure a clear and auditable process is in place for providing assessment decisions and feedback to all relevant stakeholders • have no direct connection with the apprentice, their employer or training provider. In all instances, including when the EPAO is the training provider (i.e. HEI), there must be no conflict of interest • have policies and procedures for internal quality assurance (IQA), and maintain records of regular and robust IQA activity and moderation for external quality assurance (EQA) purposes • deliver induction training for independent assessors, and for invigilators and/or markers (where used)

	• undertake standardisation activity on this apprenticeship standard for all independent assessors before they conduct an EPA for the first time, if the EPA is updated, and periodically as appropriate (a minimum of annually) • manage invigilation of apprentices in order to maintain security of the assessment in line with the EPAO's malpractice policy • verify the identity of the apprentice being assessed • use language in the development and delivery of the EPA that is appropriate to the level of the occupational standard • provide details of the independent assessor's name and contact details to the employer • have, and apply, an appropriate EPA appeals process • request certification via the Apprenticeship Service upon successful achievement of the EPA
Independent assessor	As a minimum, an independent assessor should: • have the competence to assess the apprentice at this level and hold any required qualifications and experience in line with the requirements of the independent assessor as detailed in the IQA section of this EPA plan • understand the occupational standard and the requirements of this EPA • have, maintain and be able to evidence up-to-date knowledge and expertise of the subject matter • deliver the end-point assessment in line with the EPA plan • comply with the IQA requirements of the EPAO • have no direct connection or conflict of interest with the apprentice, their employer or training provider; in all instances, including when the EPAO is the training provider (i.e. HEI) • attend induction training • attend standardisation events when they begin working for the EPAO, before they conduct an EPA for the first time and a minimum of annually on this apprenticeship standard • assess each assessment method, as determined by the EPA plan, and without extending the EPA unnecessarily • assess against the KSBs assigned to each assessment method, as shown in the mapping of

	assessment methods and as determined by the EPAO, and without extending the EPA unnecessarily • make all grading decisions • record and report all assessment outcome decisions for each apprentice, following instructions and using assessment recording documentation provided by the EPAO, in a timely manner • use language in the development and delivery of the EPA that is appropriate to the level of the occupational standard •
Training provider	As a minimum the training provider should: • work with the employer and support the apprentice during the off-the-job training to provide the opportunities to develop the knowledge, skills and behaviours as listed in the occupational standard • conduct training covering any knowledge, skill or behaviour requirement agreed as part of the Commitment Statement (often known as the Individual Learning Plan). • monitor the apprentice's progress during any training provider led on-programme learning • advise the employer, upon request, on the apprentice's readiness for EPA • remain independent from delivery of the EPA. Where the training provider is the EPA (i.e. a HEI) there must be procedures in place to mitigate against any conflict of interest

Internal Quality Assurance (IQA)

Internal quality assurance refers to the strategies, policies and procedures that EPAOs must have in place to ensure valid, consistent and reliable end-point assessment decisions. EPAOs for this EPA must adhere to all requirements within the Roles and Responsibilities section and:

- appoint and approve independent assessors to conduct marking and grading of the EPA. Appointment of independent assessors will be based on a check of occupational knowledge including current professional registration. Minimum occupational knowledge will include a minimum of 2 years' experience working in the field of Clinical Pharmacology in a clinical, industry and/or educational setting at least at the same level of the apprentice and a minimum of 2 years' experience in making performance assessment judgements.
- appoint independent assessors who are members of relevant professional bodies
- appoint independent assessors who are competent to deliver the end-point assessment
- provide training for independent assessors in terms of good assessment practice, operating the assessment tools and grading
- have robust quality assurance systems and procedures that support fair, reliable and consistent assessment across the organisation and over time
- operate induction training and standardisation events for independent assessors when they begin working for the EPAO on this standard and before they deliver an updated assessment method for the first time
- ensure independent assessors attend standardisation events on an ongoing basis and at least once per year

Affordability

Affordability of the EPA will be aided by considering the following practice:

- using an employer's premises
- videoconferencing

Professional body recognition

This apprenticeship is designed to prepare successful apprentices to meet the requirements for recognition as a full member of the British Pharmacological Society.

Mapping of knowledge, skills and behaviours (KSBs)

Assessment method 1: Project and presentation

Knowledge
K6 Analysis and interpretation: • K6.1 The role of data visualisation, summarisation and analysis • K6.2 The role of an analysis plan and its component parts • K6.3 The principles, limitations and appropriate application of various standard quantitative techniques (e.g. non-compartmental analysis, population modelling, physiologically based pharmacokinetic modelling) • K6.4The scope and capabilities of both typical and innovative bioanalytical techniques used for end-point analysis • K6.5 Methods of data research, review and synthesis
K8 The interconnected role of the clinical pharmacology scientist: • K8.1 The impact of clinical pharmacology on key decision points during drug development, and the information required to enable informed decisions • K8.2 The environments in which clinical pharmacology scientists work • K8.3 The other roles/stakeholders/bodies that interact with clinical pharmacologists and the exchanges that will need to be conducted • K8.4 The impact of clinical pharmacology on the success of the project (e.g. scientific validity, commercial, key risk areas)
K11 Effective communication: • K11.1 How to assess the needs of stakeholders and tailor effective written and verbal communications to them • K11.2 The scope and impact of different communication methods

Skills
S5 Interpretation of clinical study data: • S5.1 Contribute to analysis plans that describe how data will be analysed, summarised and graphically displayed • S5.2 Select and apply the most appropriate method of data visualisation and analysis • S5.3 Interpret data during study delivery for any interim decision points and for final study reporting discussions and conclusions • S5.4 Interpret the collated output from across multiple clinical studies
S6 Critical evaluation and decision making (part): • S6.1 Contextualise results based on other internal and external information • S6.2 Demonstrate aptitude in integrating information from a range of sources and critically evaluate it • S6.3 Identify the implications of new data and make appropriate decisions (e.g. about study design and timing)

S8 Effective communication:

- S8.1 Communicate effectively about their work and/or the work of their team to specialist and non-specialist audiences (e.g. oral presentation, protocols, consent forms and scientific reports)
- S8.2 Write scientific and technical documents that clearly convey interpretation and impact of findings
- S8.3 Discuss work constructively and objectively with internal and external stakeholders

S10 Learning and development (part):

- S10.1 Research, critique and assess new techniques and methodologies

Behaviours

B1 Integrity and reliability:

- B1.1 The ability to work with integrity, showing respect for the confidentiality of information, taking responsibility for actions and with an intrinsic ethical stance to all aspects of day-to-day activities, ensuring actions are in the best interest of stakeholders.
- B1.2 Work using the principles of the scientific method and with a concern for maximising the scientific value of a study or dataset

B2 Flexibility and adaptability:

- B2.1 A professional approach, no matter what challenges emerge.
- B2.2 A willingness to consider the broader context of project and stakeholder needs.
- B2.3 A willingness to engage with innovative practices and make suggestions for improvements.
- B2.4 An ability to adjust to, function and flourish in a diverse environment

B4 Advise and support:

- B4.1 The ability to address comments or questions by drawing upon clinical pharmacology expertise and the application of broader principles and knowledge.
- B4.2 The ability to identify uncertainties when making decisions and to highlight these, including any assumptions and limitations.
- B4.3 An awareness of limits of knowledge and competence, operating within those limits.

B6 Planning, prioritisation and organisation:

- B6.1 Effective time management, organisation, and appropriate prioritisation, setting projects in the wider context and fiscal environment.
- B6.2 Takes the initiative, working independently and coordinating effectively with others to deliver.

Assessment method 2: Professional discussion underpinned by portfolio

Knowledge
K1 Theoretical principles of drug action: • K1.1 How drugs interact with their targets, including drug-receptor theory and mechanisms of action • K1.2 The principles pharmacokinetics (including Absorption Distribution Metabolism and Excretion), toxicokinetics and pharmacodynamics and their inter-relationship • K1.3 The principles of toxicology, their application in safety assessment and in determination of the therapeutic index (the balance of safety versus efficacy in relation to dose) • K1.4 How a drug's formulation and characteristics (e.g. bioavailability, permeability, solubility, formulation, gastrointestinal pH, prandial state) can affect how it performs in the body and impact upon dose selection
K2 Dose determination: • K2.1 The principles of pre-clinical safety testing, determination of safety margins and how they affect selection of appropriate clinical dose levels • K2.2 The principles of using preclinical data to predict both human Pharmacokinetic/Pharmacodynamic (PKPD) and determine the appropriate dose • K2.3 The principles of starting dose calculation and trial progression (including dose escalation)

K3 Study design and delivery:
• K3.1 The types of pharmacology studies that are required/optional and whether to include and conduct them
• K3.2 How the following impact upon on dose selection, study design and outcomes:
  ○ Drug-drug interaction;
  ○ Organ impairment;
  ○ Age;
  ○ Intrinsic factors (e.g. population);
  ○ Extrinsic factors (e.g. food).
• K3.3 Pharmacology-related stopping criteria employed in the early phase studies
• K3.4 How to evaluate, monitor and address relevant risks to study delivery
• K3.5 The principles of risk-benefit analysis in relation to patient management
• K3.6 Standard, adaptive and other novel study designs, when to use them and the associated risks
• K3.7 The impact of immunogenicity on the PKPD of biotherapeutics
• K3.8 Optimisation of sampling timepoints
• K3.9 Trial progression strategies and how to use them appropriately (e.g. dose escalation)
• K3.10 Common types of protocol deviations that confound study results, impact the interpretation of results and may put subjects at undue risk
• K3.11 The principles of go-no-go decision matrices
• K3.12 The resource associated with clinical pharmacology studies (e.g. cost, timeframes)

K4 Study reporting and documentation: • K4.1 Content and generation of study documents (design synopsis, protocol, study report synopsis, clinical study report)

- K4.2 Reporting guidelines and best practice for documenting data, analysis processes and archiving to ensure reproducible results
- K4.3 Common types of protocol deviation that can impact on results and data interpretation

K5 The appropriate use of statistics:

- K5.1 Essential statistical principles and tests used in the life sciences (e.g. sample size, power calculations) and in the design of clinical trials
- K5.2 Statistical concepts and tools for data analysis and data interpretation in different situations (e.g. big data, sparse data, missing data)
- K5.3 The principles of powering, estimation and modelling approaches including when to apply them to a particular study

K7 Legal and regulatory principles:

- K7.1 The principles of Good Clinical Practice (GCP), Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP) and Good Documentation Practice (GDocP)
- K7.2 Laws and relevant regulatory/guidance documents, including regional differences where appropriate
- K7.3 Regulatory processes and review cycle timelines
- K7.4 Licencing requirements
- K7.5 The clinical pharmacology content in drug labelling
- K7.6 The clinical pharmacology components of the marketing application
- K7.7 Data protection and confidentiality requirements when preparing materials (e.g. redaction, re-labelling and referencing public domain case studies)
- K7.8 The principles of quality control, quality assurance and report processes
- K7.9 The principles of ethical business practice and relevant codes of conduct
- K7.10 The principles of research ethics and application to clinical trials and how these may differ for vulnerable populations (e.g. paediatrics, elderly)

K9 Drug discovery and development:

- K9.1 The stages of drug discovery and development
- K9.2 The principles of preclinical to clinical translation, translational research and experimental medicine. To include how biomarkers relate to disease processes and drug mechanism of action, and can be related to clinical safety and efficacy endpoints
- K9.3 The principles of reduction, refinement and replacement in the use of animals in research
- K9.4 How the principles of clinical pharmacology apply to new therapeutic approaches (e.g. cell-based therapies, antibody-drug conjugates, oncolytic viruses, Ribonucleic Acids [RNAs])
- K9.5 The principles of pharmacogenomics and impact on drug development
- K9.6 Innovative drug delivery and formulations

K10 Learning and development:

- K10.1 The principles of learning and developing in the workplace, including ethical and safe practices with regards to coaching and mentoring (e.g. appropriate interactions, confidentiality)
- K10.2 The principles of, and good practice relating to, equality and diversity in the workplace
- K10.3 An awareness of relevant workplace leadership strategies and skills, including matrix leadership and change management in a scientific organisation

Skills

S1 Dose determination:

- S1.1 Calculate safe and efficacious human dose predictions (amount and schedule) from pharmacokinetic and toxicokinetic pre-clinical data using quantitative pharmacology methods (e.g. by allometry or physiologically based modelling)
- S1.2 Calculate recommended safe dose for first administration to humans based on pre-clinical data
- S1.3 Make predictions regarding viability/safety of additional dose levels and the likelihood of the effectiveness of a dose reduction strategy relative to maintaining an appropriate therapeutic window
- S1.4 Make recommendations about appropriate trial progression strategies (e.g. dose escalation)
- S1.5 Select and interpret data from a range of relevant sources (e.g. in silico models, biochemistry tests) in order to determine suitable doses for specific populations.

S2 Study design and delivery:

- S2.1 Perform robust data reviews, including appropriate extrapolation from available knowledge and data, and the use of appropriate techniques to determine the potential for clinically relevant drug-drug interactions
- S2.2 Design efficient, safe, scientifically robust and feasible study protocols and support the design of bespoke clinical pharmacology development plans. Design should consider preclinical data and the impact of external factors (e.g. characteristics of the drug, budgetary, competitive landscape) and use appropriate powering, estimation, modelling and adaptive approaches where applicable.
- S2.3 Optimise study assessments (e.g. the type and timing of pharmacokinetic sampling, biomarkers and other assessments) taking into account both study needs and subject well-being, and including appropriate assessment criteria (e.g. interim and final) for analysis
- S2.4 Consider and propose methods (e.g. physiologically based pharmacokinetic modelling) alternative to clinical studies when appropriate
- S2.5 Contribute to the design and execution of go-no-go decisions

S3 Study reporting and documentation:

- S3.1 Write flexible and robust protocols
- S3.2 Make relevant contributions to clinical study reports
- S3.3 Interpret data and contextualise results (Interim and Final)

S4 The appropriate use of statistics:

- S4.1 Interpret statistical results appropriately (e.g. when summarising study outcomes)
- S4.2 Use appropriate software and graphical exploration to perform data analysis (e.g. exposure response, exposure safety)
- S4.3 Apply appropriate statistical techniques when analysing and summarising study outcomes, with support from statisticians where necessary

S6 Critical evaluation and decision making (part):

- S6.4 Identify potential gaps in the clinical pharmacology understanding of a new molecular or biological entity

S7 Legal and regulatory principles:

- S7.1 Complete the required clinical pharmacology components of clinical trial application and a licensing application
- S7.2 Contribute to writing the drug label
- S7.3 Develop and write relevant components of regulatory documents (e.g. investigator brochure, protocol, informed consent document)

- S7.4 Interpret questions and feedback from regulatory, ethics and other review bodies and formulate appropriately detailed and clear responses
- S7.5 Data protection and confidentiality requirements and avoid breaches

S9 Study management:

- S9.1 Assess risks to delivering a protocol for the clinical pharmacology package and formulate mitigation plans
- S9.2 Redact, relabel and reference public domain case studies to avoid confidentiality breaches

S10 Learning and development (part):

- S10.2 listen to learners to assess their understanding and adapt techniques to their needs, using ethical and safe practices when mentoring, coaching and training others

Behaviours

B3 Team Working:

- B3.1 The ability to lead group activities to arrive at a common goal.
- B3.2 The ability to listen to a wide range of views and be inclusive when seeking input.
- B3.3 An ability to work in a team, demonstrating respect for colleagues and the viewpoints of others.
- B3.4 A willingness to share knowledge and expertise with others.
- B3.5 The ability to maintain effective working relationships and collaborations

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B5 "Patients First" Attitude:

- Puts the patient first and respects their contribution by ensuring they are fully informed, and their views inform decision making processes

B7 Continuing professional development (CPD):

- B7.1 Recognition of the importance of CPD and a commitment to lifelong learning in personal development and the support of others
- B7.2 Demonstrates curiosity, keeps up to date with relevant developments and proactively develops knowledge to ensure that scientific and business decisions are based on strong science.

Grading descriptors

Assessment method 1: Project and presentation

KSBs	Fail	Pass **Apprentices must achieve all of the following:**	Distinction **Apprentices must achieve all of the pass requirements and at least 3 of the following 4 statements:**
K8.1, K8.2, K8.3, K8.4	Does not meet the pass criteria	Describes the clinical pharmacology scientist role and the impact it has on key decision points and the success of the project. (K8.1, K8.2, K8.4) Can point to commonalities and differences between this role and that of others in the team (K8.3)	Critically appraise the interconnected nature of the Clinical Pharmacologists role with a deep understanding of the skills and attributes that allow effective and safe study completion. (K8.1, K8.2, K8.3, K8.4)
K6.1, K6.2, K6.3, K6.4, K6.5, S5.1, S5.2, S5.3, S5.4, B1.2, B2.1, B2.2, B4.1, B4.2, B4.3		Assembles and presents data from standard clinical pharmacology studies at both interim and study completion points. Researches and interprets the meaning of data from typical and innovative bioanalytical quantitative techniques and highlights implications and assumptions made. (K6.1, K6.2, K6.3, K6.4, K6.5, S5.1, S5.2, S5.3, S5.4, B1.2, B2.1, B2.2, B4.1, B4.2, B4.3)	Research, analyse and interpret complex clinical pharmacology data sets at both interim and study completion points. Can appraise the strengths and weaknesses of the bioanalytical techniques. Shows the ability to effectively adapt to arising problems in studies and provide a reflective appraisal of potential errors in the study and understands risks and risk mitigation (K6.1, K6.2, K6.3, K6.4, K6.5, S5.1, S5.2, S5.3, S5.4)
S6.1, S6.2,		Integrates data from both external and internal data sources and explains how	Critically evaluates the implications of both internal and external data on their own projects and this influences the

S6.3; B2.4		new data can impact upon decision making (S6.1, S6.2, S6.3, B2.4)	wider context of the project work and its findings. Demonstrates the ability to plan and execute effective strategies to deal with data gaps and can mitigate their influence on the final study outcome (S6.1, S6.2, S6.3)
K11.1, K11.2, S8.1, S8.2, S8.3, B1.1 B6.1 B6.2		Can communicate a variety of topics (specialist and non-specialist) constructively and objectively with internal and external audiences. Can write technical and scientific documents that clearly convey interpretation and have impact of findings on different audiences (K11.1, K11.2, S8.1, S8.2, S8.3, B1.1, B6.1, B6.2)	Appraises and evaluates the impact of new methodology within the workplace, and linked to clinical studies and data generation, articulates considerations for when use of such methodology is appropriate (S10.1, B2.3)
S10.1, B2.3		Can apply new techniques/methodologies to improve practice (S10.1, B2.3)	

Assessment method 2: Professional discussion underpinned by portfolio

KSBs	Fail	Pass Apprentices must achieve all of the following:	Distinction Apprentices must achieve all of the pass requirements and at least 3 of the following 5 statements:
K9.1, K9.2, K9.3, K9.4, K9.5, K9.6	Does not meet the pass criteria	Describes the drug discovery and development process, the use of animal and human subjects in translational research. Understand the utility of biomarkers and can name 3 innovations (e.g. pharmacogenomics, new therapeutic approaches) that may impact on clinical pharmacology requirements (K9.1, K9.2, K9.3, K9.4, K9.5, K9.6)	Appraises the impact of innovative approaches (e.g. new therapeutic modalities), using literature and/or data packages to justify modifications to clinical pharmacology requirements or methodologies (K9.1, K9.2, K9.3, K9.4, K9.5, K9.6)
K3.1, K3.2, K3.3, K3.4, K3.5, K3.6, K3.7, K3.8, K3.9, K3.10, K3.11, K3.12, S2.1, S2.2, S2.3, S2.4, S2.5		Can identify efficient, safe, scientifically robust and feasible study protocols, considering the importance of appropriate design and clinical, safety and pharmacokinetic end points (K3.1, K3.2, K3.3, K3.4, K3.5, K3.6, K3.7, K3.8, K3.9, K3.10, K3.11, K3.12, S2.1, S2.2, S2.3, S2.4, S2.5,)	Uses innovative approaches to conducting pharmacology study designs. Shows evidence of using a new type of study design, a novel end-point or approach to complete a study safely and successfully (K3.1, K3.2, K3.3, K3.4, K3.5, K3.6, K3.7, K3.8, K3.9, K3.10, K3.11, K3.12, S2.1, S2.2, S2.3, S2.4, S2.5)
K4.1, K4.2, K4.3, S3.1,		Can effectively interpret all data arising from a clinical pharmacology study using a full suite of appropriate documents (including study deviation documents) so that subsequent data reporting and documentation considers the specifics of the protocol	

S3.2, S3.3		and its broader context (K4.1, K4.2, K4.3, S3.1, S3.2, S3.3,)	
S4.1, S4.2, S4.3, K5.1, K5.2, K5.3		Evaluates the advantages and limitations of statistical approaches, interpretation and software use. Show evidence of referral to a statistician at appropriate points in a study and can use statistical software to view and perform basic statistical analysis (S4.1, S4.2, S4.3, K5.1, K5.2, K5.3)	
S7.1, S7.2, S7.3, S7.4, S7.5, K7.1, K7.2, K7.3, K7.4, K7.5, K7.6, K7.7, K7.8, K7.9, K7.10		Evidences contribution to regulatory and licencing processes, including GLP, GMP, GCP, labelling and marketing authorisation processes. Shows an ability to respond to regulatory questions on the regulatory compliance. Can contribute regulatory documents and understands both the impact of confidentiality and ethics (S7.1, S7.2, S7.3, S7.4, S7.5, K7.1, K7.2, K7.3, K7.4, K7.5, K7.6, K7.7, K7.8, K7.9, K7.10)	Explains how to design studies that are compliant to regulatory guidelines such as GLP, GMP, GCP, labelling and marketing authorisation. Understands the concept of non-compliance and can detail the impact of this on a study. Can put in place procedures that mitigate against study non-compliance to regulatory guidelines (K7.1, K7.2, K7.3, K7.4, K7.5, K7.6, K7.7, K7.8, K7.9, K7.10)
K10.1, K10.2, K10.3		Identifies different leadership styles and strategies, showing consideration for principles of learning development equality, diversity and ethical practice in the workplace (K10.1, K10.2, K10.3)	
K1.1, K1.2,			

K1.3, K1.4 K2.1, K2.2, K2.3 S1.1, S1.2, S1.3, S1.4, S1.5, B7.2		Understands the basic pharmacology that underpins a study including the target receptor, binding and off-target toxicological effects. Understands the basic properties of the drug molecule including both chemical and physical properties. Uses this basic information to calculate safe and efficacious doses, and designs appropriate progression strategies for different drugs and different drug formulations (K1.1, K1.2, 1.3, K1.4, K2.1, K2.2, K2.3, S1.1, S1.2, S1.3, S1.4, S1.5, B7.2)	Appraises the different methods by which safe and efficacious doses can be calculated based on clinical and pharmacology data and designs the most efficient progression strategies for different drugs and different drug formulations (K1.1, K1.2, 1.3, K1.4, K2.1, K2.2, K2.3, S1.1, S1.2, S1.3,)
S9.1, S9.2		Explains the importance of risk management plans and links these to mitigation strategies especially in the domain of confidentiality breaches (S9.1, S9.2)	
S6.4		Can identify data gaps in a clinical pharmacology study and can minimize their impact on the study outcomes (S6.4)	Can use mitigation strategies to prevent critical gaps occurring in clinical pharmacology studies (S6.4)
S10.2, B3.4		Evidences ability to listen to a colleague and help them to develop new knowledge or a new skill (S10.2, B3.4)	
B3.1, B3.3,		Evidences leading a group activity to achieve a common goal (B3.1, B3.3) Evidences effective collaborative work and	

B3.2, B3.5 B5 B7.1		describes how the views of others informed decisions (B3.2, B3.5) Evidences prioritisation of patient safety and using patient views to inform decisions(B5) Evidences active engagement with their own CPD and supports others in theirs. (B7.1)	